

## DETAILED ACTION

### ***Response to Amendment***

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Douk (US Pg Pub 2005/0027236)**, herein after referred to as **D**, in view of **Gay et al. (US Patent 5047018)**, herein after referred to as **G and Schwager (US Pg Pub 2001/0007922)**, herein after referred to as **S**.

Regarding **Claim 1**, D discloses a guidewire shaft (**112**, guidewire shaft) disposed at the distal region of the distal shaft, the guidewire shaft having a guidewire

lumen into which a guidewire is insertable, the guidewire lumen being disposed in the guidewire shaft; a hub (**120**, hub) provided at the proximal end of the proximal shaft, the aspiration lumen extending to the hub;

**D** fails to disclose the proper main shaft and a detachable core wire disposed in the aspiration lumen.

**However, S** teaches a main shaft including a distal shaft (8) and a proximal shaft, (3)wherein an aspiration lumen (4, this lumen is capable of performing this task)for removing the substance by aspiration is disposed in the distal shaft and the proximal shaft; a detachable core wire (70, the independent wire) disposed in the aspiration lumen: wherein the relationship  $0.4 < R1/R2 < 0.7$  is satisfied, wherein R1 is a maximum outer diameter of the core. wire, and R2 is a minimum inner diameter of the aspiration lumen located on the distal side of the hub.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the wire separable, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Nerwin v. Erlichman, 168 USPQ 177, 179.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the wire diameter the proper size, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

However, **G** teaches a detachable core wire (**28**) disposed in the aspiration lumen wherein the distal end of the core wire recedes from the distal end of the aspiration lumen in the proximal direction (**Fig. 1 and 2**).

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the core as taught by **G**, since **G** states at Column 2 lines 1-35 that such modification would allow for ease of delivery. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in **G**, to improve the device of **D** for the predictable result of making it more mobile.

Regarding **Claim 2**, **G** discloses: a connector (**26**, the handle) is fixed on the proximal end of the core wire, and the connector is mounted to the proximal end of the hub in a detachable manner.

Regarding **Claim 3**, **G** discloses: the interior of the aspiration lumen can be flushed through the connector with the connector being mounted to the proximal end of the hub in a detachable manner. (**Fig. 2**, the core does not interfere with the lumen).

Regarding **Claim 7**, **G** discloses: the core wire is a spring wire comprising a coiled metal wire. (**14**).

Regarding **Claim 8**, **G** discloses: at least a portion of the core wire has a tapered shape (**28**, the end tapers) in which the outer diameter becomes larger toward the proximal end..

Regarding **Claim 9**, **G** discloses: at least a portion of the core wire has flexibility which becomes higher toward the distal end. (**14**).

1. Claims 10-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **D, S and G**, in view of **Noriega et al. (US Pg Pub 2005/0119615)**, herein after referred to as **N**.

Regarding **Claim 10, N** discloses: the core wire comprises stainless steel, a Co-Cr alloy, an Ni-Ti alloy, an Ni-Ti-Fe alloy, an Ni-Ti-Cu alloy, an Ni-Ti-Cr alloy, an Ni-Ti-V alloy, an Ni-Ti-Co alloy, an Ni-Ti-Nb alloy, an Ni-Ti-Pd alloy, an Ni-Ti-Cu-Cr alloy, or a composite thereof. (**Paragraph 80**).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the proper material. Since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding **Claims 11 and 12, D** discloses: the invention as claimed above except for the proper L relationship.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the proper range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding **Claim 13, N** discloses: a radiopaque marker. (**36, radiopaque marker**).

Regarding **Claim 14, D** discloses: a polyimide. (**Paragraph 27**).

Regarding **Claim 15, N** discloses: a braided tube (**Fig. 10**, braid and polymer) in which a metal braid and a polymer material are combined.

Regarding **Claim 16**, **N** discloses: an inner layer (**Fig. 3A**) defining the aspiration lumen, a metal braid disposed on the outer surface of the inner layer, and an outer layer disposed on the outer surface of the metal braid.

Regarding **Claim 17**, **D** discloses: the invention as claimed above except for the proper flexural modulus.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the flexibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claim 19 **D** discloses the steps of inserting the aspiration catheter into a living body with the core wire being present in the aspiration lumen, then withdrawing the core wire, and applying a negative pressure to the aspiration lumen to remove by aspiration a substance from the living body(**Paragraph 45-47**)

Regarding claim 20, **N** discloses the core wire has a straight shape (Fig 2, the wire is straight)

4. Claim 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **D, S, G, and N**, in view of *Ha et al.* (US Patent 6159195).

Regarding **Claim 18**, **D** discloses the invention claimed above except for the coating.

However *Ha* teaches at least a portion of the distal shaft is applied with a hydrophilic coating (**Column 6, lines 13-19**, hydrophilic coating well known in the art) that exhibits a lubricating property in a wet environment.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the coating since it was known in the art that coatings are commonly applied.

Applicant's arguments filed have been fully considered but they are not persuasive.

***Response to Arguments***

**Applicant states**, the amended claims differentiate over the prior art, however, the claims remain rejected in view of the new grounds of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN K. HOLLOWAY whose telephone number is (571)270-3862. The examiner can normally be reached on 8-5, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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